DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 21, 2015

ConvaTec, Ltd.
Clare Williamson
Regulatory Affairs Documentation Compliance Manager
Unit 20, First Avenue, Deeside Industrial Park
Deeside, Flintshire CH5 2NU
UK

Re: K150350
Trade/Device Name: Flexi-Seal® Signal™ Fecal Management System
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: June 18, 2015
Received: June 24, 2015

Dear Clare Williamson,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150350

Device Name

Flexi-Seal® Signal™ Fecal Management System

Indications for Use *(Describe)*

For use to manage fecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Unit 20, First Avenue
Deeside Industrial Park
Deeside
Flintshire CH5 2NU
Telephone: 01244 584000
Facsimile: 01244 584011

510(k) Summary

Subject Device: Flexi-Seal® SIGNAL™ Fecal Management System

Date Prepared: February 06, 2015

Applicant: ConvaTec Ltd.

First Avenue
Deeside Industrial Park
Deeside
Flintshire CH5 2NU
UK

Contact: Clare Williamson

Regulatory Affairs Documentation Compliance Manager
Tel: +44 (0)1244 584155
Fax: +44 (0)1244 584311
Email: clare.williamson@convatec.com

Device Trade Name: Flexi-Seal® SIGNAL™ Fecal Management System

Common Name: Fecal Management System

Classification Name: Gastrointestinal Tube and Accessories (21 CFR §876.5980, Product Code: KNT)

Device Class: Class II

Predicate Device:

Device Trade Name: Flexi-Seal® SIGNAL™ Fecal Management System - ConvaTec Inc.

Common Name: Fecal Management System

Classification Name: Gastrointestinal Tube and Accessories (21 CFR §876.5980, Product Code: KNT)

Device Class: Class II

510(k) Substantial Equivalence: K112342 - determined substantially equivalent on April 26, 2012

Device Description:

The Flexi-Seal® SIGNAL™ Fecal Management System is comprised of a soft catheter tube assembly, a Luer-lock syringe, a collection bag with cap and a cinch clamp to pinch off flow in the catheter when required for medication retention or to stop waste flow. The components are contained in a rigid thermoformed plastic clamshell.

The catheter main drain tube is fabricated from collapsible silicone rubber with the addition of an odor adsorber, which is added in order to help contain the fecal odor which often permeates through the wall of the catheter.

The drain tube has a low-pressure silicone retention balloon at the distal end and a connector for attaching a collection bag (provided with the device and also available separately) at the proximal end. There is a recess (pocket) under the balloon for the clinician's finger, which allows the device to be positioned digitally.

Two ports are attached to the side of the catheter. One port is used to inflate the retention balloon with water or saline after the device has been inserted into the patient's rectum. This port also provides a visual and tactile signal of when the low pressure retention balloon is filled to its optimal volume. The other port is used to flush the device if needed and administer medication if prescribed.

An additional sampling port is located on the side of the catheter, which allows access to clinicians for stool sample collection.

A syringe (provided with the device) is used to fill and evacuate the retention balloon for insertion and removal.

The device, collection bag and syringe are intended for single us, are provided non-sterile and contain no components made with animal products, natural rubber latex or DEHP.

This Traditional 510(k) concerns modifications which do not alter the indications for use of the predicate device, the Flexi-Seal® SIGNAL™ Fecal Management System (ref. K112342).

Intended use:

The Flexi-Seal® SIGNAL™ Fecal Management System is an indwelling fecal management catheter intended for use to manage fecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications. The device is not intended for use on pediatric patients.

Summary of Technological Characteristics:

The Flexi-Seal® SIGNAL™ Fecal Management System has the same intended use and indications for use as the predicate device, however the tubing now incorporates odor adsorbing properties. The adsorber reduces the odor which often permeates through the wall of the catheter. These unpleasant odors during catheter use can cause major discomfort to the patients, caregivers and visitors. Therefore, the reduction of odor is advantageous to overall patient wellbeing.

The device specifications are essentially identical to those of the predicate device, although minor adjustments have been made to the catheter tubing to

ensure that the material softness remains. Catheter tube diameter, catheter tube hardness, catheter tube tensile strength, and balloon-catheter bonding were evaluated via bench testing and are substantially equivalent to the predicate device. There are no differences in operation between the Flexi-Seal® SIGNAL™ Fecal Management System and the predicate device.

Summary of Performance (Non-Clinical Testing) Data:

Non-clinical testing of the subject device for functional and structural parameters has been performed. In this testing, the device's performance has been found to be substantially equivalent to the aforementioned predicate device both functionally and structurally (material strength, catheter size, balloon size, etc.). The device has also been evaluated for biocompatibility in accordance with the US Food and Drug Administration's guidance entitled *Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'*, issued May 1, 1995, and has been found safe in such respect for its intended use.

In conclusion, the subject device has been demonstrated as safe and effective and substantially equivalent to the predicate device.

Summary of Technological Characteristics

The following table summarises the technological characteristics of the subject and predicate devices (ref. K112342, determined substantially equivalent on April 26, 2012) and outlines the product characteristics and specifications which form the basis of the substantial equivalence discussion.

The intended use, technological characteristics and principles of operation of the Flexi-Seal® SIGNAL™ Fecal Management System remains the same as those of the predicate device.

Parameter	Subject Device	Predicate	Comparison	
	Flexi-Seal® SIGNAL™ Fecal Management System	Flexi-Seal® SIGNAL™ Fecal Management System (K112342)	Similarities	Differences
FDA Product Code	KNT	KNT	Both devices are the same	None
FDA Classification Regulation	21 CFR 876.5980	21 CFR 876.5980	Both devices are the same	None
Regulatory Class	Class II	Class II	Both devices are the same	None
Intended Use	To manage fecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications	To manage fecal incontinence through the collection of liquid to semi-liquid stool and to provide access to administer medications	Both devices are the same	None
Functional configuration	Collapsible catheter with distal end secured in the rectum and proximal end connected to a collection bag	Collapsible catheter with distal end secured in the rectum and proximal end connected to a collection bag	Both devices are the same	None
Retention feature	Soft annular balloon	Soft annular balloon	Both devices are the same	None
Balloon material	Silicone rubber	Silicone rubber	Both devices are the same	None
Inflation management	Sealed water filled balloon	Sealed water filled balloon	Both devices are the same	None
Retention balloon inflation material	Water/saline (45ml)	Water/saline (45ml)	Both devices are the same	None
Catheter tube length	1,550mm - 1,670mm	1,550mm - 1,670mm	Both devices are the same	None
Length of sphincter section	>10cm	>10cm	Both devices are the same	None

Parameter	Subject Device	Predicate	Comparison	
	Flexi-Seal® SIGNAL™ Fecal Management System	Flexi-Seal® SIGNAL™ Fecal Management System (K112342)	Similarities	Differences
Drain channel	Large main drain tube	Large main drain tube	Both devices are the same	None
Inflation and irrigation port connections	Luer	Luer	Both devices are the same	None
Inflation lumen diameter	Two lumens at 1.45 mm	Two lumens at 1.45 mm	Both devices are the same	None
Inflation lines	2	2	Both devices are the same	None
Irrigation lines	1	1	Both devices are the same	None
Sampling port	Closable snap seal for catheter syringe access	Closable snap seal for catheter syringe access	Both devices are the same	None
Collection bag configuration	Disposable with gas filter	Disposable with gas filter	Both devices are the same	None
Collection bag size	1 litre disposable	1 litre disposable	Both devices are the same	None
Method of bed connection	Hanging strap on bag connector	Hanging strap on bag connector	Both devices are the same	None
Accessory components	Syringe and cinch clamp	Syringe and cinch clamp	Both devices are the same	None
Flow stop mechanism	External cinch clamp	External cinch clamp	Both devices are the same	None
Sterility status (how provided)	Non-sterile	Non-sterile	Both devices are the same	None
Packaging	Thermoformed plastic clamshell	Thermoformed plastic clamshell	Both devices are the same	None